



*American Academy of Dermatology*

Darrell S. Rigel, MD  
*President*

1350 I St NW Ste 880  
Washington DC 20005-3319  
Phone 202/842-3555  
Fax 202/842-4355  
Web Site www.aad.org

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April 1, 1999

Food and Drug Administration  
Dockets Management Branch (HFA-305)  
5630 Fisher's Lane  
Room 1061  
Rockville, MD 20852

**ATTENTION:** [Docket No. 78N-0038]

Dear Sir or Madam:

I am writing on behalf of the American Academy of Dermatology regarding the proposed cap on sun protection factors (SPF). It is our hope that your agency would seriously consider our position on this issue before making a final decision.

In a meeting convened by the American Academy of Dermatology in Washington in October, 1992, we had proposed that a **floor** rather than a **cap** on SPFs was appropriate.(1) There are at least two major reasons that capping of the SPF should be avoided:

1. It is known that application of sunscreen by patients is less than the concentration used for SPF testing (2 mg/cm<sup>2</sup>). This effectively diminishes the SPF value of the sunscreen in real use.(2)
2. Using sunscreen that prevented UV- induced erythema, apoptosis and sunburn cell formation could still be detected.(3) Therefore, prevention of erythema does not completely diminished the other potential harmful effects of ultraviolet radiation. Furthermore, the formation of sunburn cells was directly proportional to the SPF number of the sunscreen, specifically, the lower SPF, the higher number of sunburn cells was noted. Recently, the lack of total protection by currently available sunscreens on carcinogenic effect of ultraviolet radiation was reported.(4)

As sunlight is considered to be a major factor in the development of non-melanoma skin cancer and malignant melanoma, it would be in the best interest of the general public to have sunscreens with high SPFs. In public education messages, from our Academy, we have emphasized that sunscreen is a component of the total sun protection, which would also include sun avoidance, the use of tightly woven clothing, and wide brim hat. It is our hope that through public education and through a joint effort with regulatory agencies and industry, that we will be able to decrease the incidence of skin cancers in our patient population.

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I would like to thank you for giving us the opportunity to provide input for your deliberation. Should you need to discuss this any further, please contact the Academy's Washington Office at 202-842-3555.

Sincerely,



Darrell Rigel, M.D., President  
American Academy of Dermatology

DR:dac

#### REFERENCES

1. National Conference on Environmental Hazards to the skin, October 15-16. Comprehensive position Statement, American Academy of Dermatology (1992).
2. Wulf HC, Stender IM, Lock-Andersen J. Sunscreens used at the beach do not protect against erythema: a new definition of SPF is proposed. *Photodermatol Photoimmunol Photomed.* 1997;13:129-32.
3. Kaidbey KH. The photoprotective potential of the new superpotent sunscreens. *J Amer Acad Dermatol.* 1990;22:449-452.
4. Young A. Sunscreens: Photoprotection of non-erythema endpoints relevant to skin cancer. Presented at the annual meeting of the Photomedicine Society, New Orleans, LA, March 18, 1999.